

BIOENGINEERING RESEARCH PARTNERSHIPS

RELEASE DATE: November 18, 2003

PA NUMBER: PAR-04-023

EXPIRATION DATE: August 22, 2006

Department of Health and Human Services (DHHS)

PARTICIPATING ORGANIZATION:

National Institutes of Health (NIH)

(<http://www.nih.gov>)

COMPONENTS OF PARTICIPATING ORGANIZATION:

National Cancer Institute (NCI)

(<http://www.nci.nih.gov>)

National Eye Institute (NEI)

(<http://www.nei.nih.gov>)

National Heart, Lung, and Blood Institute (NHLBI)

(<http://www.nhlbi.nih.gov>)

National Human Genome Research Institute (NHGRI)

(<http://www.nhgri.nih.gov>)

National Institute on Aging (NIA)

(<http://www.nia.nih.gov>)

National Institute of Allergy and Infectious Diseases (NIAID)

(<http://www.niaid.nih.gov>)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

(<http://www.niams.nih.gov>)

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

(<http://www.nibib.nih.gov>)

National Institute of Child Health and Human Development (NICHD)

(<http://www.nichd.nih.gov>)

National Institute on Drug Abuse (NIDA)

(<http://www.nida.nih.gov>)

National Institute on Deafness and Other Communication Disorders (NIDCD)

(<http://www.nidcd.nih.gov>)

National Institute of Dental and Craniofacial Research (NIDCR)

(<http://www.nidcr.nih.gov>)

National Institute of Environmental Health Sciences (NIEHS)

(<http://www.niehs.nih.gov>)

National Institute of General Medical Sciences (NIGMS)

(<http://www.nigms.nih.gov>)

National Institute of Neurological Disorders and Stroke (NINDS)

(<http://www.ninds.nih.gov>)

National Library of Medicine (NLM)

(<http://www.nlm.nih.gov>)

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBERS: 93.286, 93.287, 93.394, 93.395, 93.396, 93.867, 93.172, 93.837, 93.838, 93.839, 93.866, 93.855, 93.856, 93.846, 93.864, 93.865, 93.929, 93.279, 93.173, 93.121, 93.113, 93.821, 93.859, 93.862, 93.853, and 93.879.

LETTER OF INTENT RECEIPT DATES: November 21, 2003; June 20, 2004; November 20, 2004; June 19, 2005; November 20, 2005; and June 22, 2006

APPLICATION RECEIPT DATES: January 21, 2004; August 20, 2004; January 20, 2005; August 19, 2005; January 20, 2006; and August 22, 2006

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PURPOSE OF THIS PA

Participating Institutes and Centers (ICs) of the National Institutes of Health (NIH) invite applications for R01 awards to support Bioengineering Research Partnerships (BRPs) for basic, applied, and translational multi-disciplinary research that addresses important biological or medical research problems. In the context of this program, a partnership is a multi-disciplinary research team that applies an integrative, systems approach to develop knowledge and/or methods to prevent, detect, diagnose, or treat disease or to understand health and behavior. The partnership must include appropriate bioengineering or allied quantitative sciences in combination with biomedical and/or clinical components. The Principal Investigator (PI) also serves as the project manager and must be capable of leading the proposed effort. A BRP may propose design-directed, developmental, discovery-driven, or hypothesis-driven research at universities, national laboratories, medical schools, large or small businesses, or other public and private entities or combinations of these entities. It is expected that a BRP will have a well-defined goal or deliverable that will be achieved based on objective milestones specified in the initial application. On October 11, 2001, the NIH issued a related program announcement (PA)

PA-02-011 (<http://grants.nih.gov/grants/guide/pa-files/PA-02-011.html>) for Bioengineering Research Grants (BRGs). The BRGs differ from the BRPs in that the research will be performed in a single laboratory, by a single investigator, or by a small group of investigators. On January 16, 2003, the NIH issued another related program announcement PA-03-058 (<http://grants.nih.gov/grants/guide/pa-files/PA-03-058.html>) for Exploratory/Developmental (R21) Bioengineering Research Grants (EBRG). The EBRGs differ from the BRPs in that (1) the research will be performed in a single laboratory, by a single investigator, or by a small group of investigators and (2) the projects are high-risk/high-payoff in nature (R21 mechanism) as compared to the R01-type grants supported by the BRP program.

RESEARCH OBJECTIVES

Many of today's biomedical problems are best addressed using a multi-disciplinary approach that extends beyond the traditional biological and clinical sciences. Bioengineering integrates principles from a diversity of technical and biomedical fields and crosses the boundaries of many scientific disciplines represented throughout academia, laboratories, and industry. The creativity of interdisciplinary teams is resulting in new basic understandings, novel products, and innovative technologies for addressing biomedical problems.

Recognizing the importance of bioengineering in public health, the Bioengineering Consortium (BECN) was established in 1997 as a focus for bioengineering activities at the NIH. To facilitate communication between the allied and biomedical disciplines and to provide input from the scientific community on research needs and directions, the BECN has held annual two-day symposia on emerging topics of interest related to bioengineering including bioengineering (1998), bioimaging, (1999), nanotechnology (2000), reparative medicine (2001), biosensors (2002), and team science (2003). Summaries of the proceedings and recommendations of these symposia are available on the Internet at http://www.becn.nih.gov/becn_symposia.htm.

Discussions and recommendations of symposia participants aided in the formulation of the BRP, BRG, and EBRG program announcements. It is expected that some applications submitted in response to the BRP, BRG, and EBRG PAs will focus on technology development rather than on proving or disproving scientific hypotheses. In support of this approach, NIH instructions to applicants and review criteria emphasize that a project may "...test a stated hypothesis, create a novel design, solve a specific problem, or develop new technology" (PHS 398 instructions for the research plan).

The primary objective of this program announcement is to encourage basic, applied, and translational bioengineering research that could make a significant contribution to improving human health. Bioengineering integrates physical, engineering, and computational science principles for the study of biology, medicine, behavior, or health.

It advances fundamental concepts, creates knowledge from the molecular to the organ systems level, and develops innovative biologicals, materials, processes, implants, devices, and informatics approaches for the prevention, diagnosis, and treatment of disease, for patient rehabilitation, and for improving health. Some BRP projects may propose research that could lead to a novel device as a product. Partnership with companies that have relevant expertise or that may eventually be involved in commercialization is appropriate under the BRP program.

A second objective is to encourage collaborations and partnerships among the allied quantitative and biomedical disciplines. A BRP must bring together the necessary physical, engineering, and computational science expertise with biological or clinical expertise and resources to address a significant area of bioengineering research within the mission of the NIH. In addition to the benefits to be derived from the research, the collaborations and partnerships can create opportunities for trans-disciplinary communication and training for a new generation of scientists capable of interacting across traditional technical boundaries.

Applications for a BRP award should focus on an area of basic, applied, translational, behavioral, or clinical research in bioengineering that supports the missions of the participating NIH institutes and centers and where progress is likely to make a significant contribution to improving human health. Some NIH institutes and centers have indicated that they will only consider BRP applications in specific focus areas. These institutes and focus areas are available at http://www.becon.nih.gov/becon_brpareas.htm.

MECHANISM OF SUPPORT

This PA uses the NIH R01 award mechanism. As an applicant, you are solely responsible for planning, directing, and executing the proposed project.

This PA uses just-in-time concepts. It also uses the modular budgeting as well as the non-modular budgeting formats (see <http://grants.nih.gov/grants/funding/modular/modular.htm>). Specifically, if you are submitting an application with direct costs in each year of \$250,000 or less, use the modular budget format. Otherwise follow the instructions for non-modular budget research grant applications. This program does not require cost sharing as defined in the current NIH Grants Policy Statement at http://grants.nih.gov/grants/policy/nihgps_2001/part_i_1.htm.

The initial period of support of a BRP award may be up to five years. The award may be competitively renewed for a total of up to ten years of NIH funding.

Competing renewal and revised applications for BRP grants are to be received at the NIH on the same receipt dates as new BRP applications.

For new grants, the maximum total (direct plus facilities and administrative [F&A] costs) budget to be awarded in any year is \$2 million. The number of awards and level of support will depend on the number of applications of high scientific merit that are received and the availability of funds. Funding in subsequent years will be contingent upon satisfactory progress during the preceding year(s) and the availability of funds. Applicants are strongly encouraged to discuss budget requests with NIH scientific and financial contacts listed under **WHERE TO SEND INQUIRIES** prior to submission.

Grantees have the authority to extend the duration of a BRP grant on a no-cost basis. This extension provides additional time to use funds that remain available at the end of the project period to continue pursuing the aims of the grant. Grantees should notify the Grants Management Officer of the awarding institute or center of the no-cost extension as early as possible and before the expiration of the grant.

ELIGIBLE INSTITUTIONS

You may submit (an) application(s) if your institution has any of the following characteristics:

- o Domestic for-profit or non-profit organizations
- o Domestic public or private institutions such as universities, colleges, hospitals, and national laboratories
- o Units of state and local governments
- o Eligible agencies of the Federal government
- o Large or small businesses
- o Faith-based or community-based organizations
- o Foreign institutions are not eligible to apply as Principal Investigators.

However, BRP collaborative projects may include work at a foreign site when the expertise at the foreign site is not present in the United States.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the leadership skills, knowledge, and resources necessary to carry out the proposed research and manage the overall effort is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are encouraged to apply for NIH programs.

SPECIAL REQUIREMENTS

RESEARCH FOCUS AREAS: Applicants are strongly advised to contact IC scientific program staff listed under **WHERE TO SEND INQUIRIES** to discuss the relevance of their proposed work to the institute's mission before preparing a detailed research application. Detailed information on research missions and programs for each NIH

institute and center is available on the participating ICs Web sites, which are listed at the beginning of this announcement. Some NIH institutes and centers have indicated that they may only want to consider BRP applications in specific focus areas. As they are available, these institutes and focus areas will be posted at http://www.becon.nih.gov/becon_brpareas.htm.

SPECIFIC INSTRUCTIONS FOR APPLICATIONS REQUESTING DIRECT COSTS OF \$500,000 OR MORE PER YEAR: Applicants requesting \$500,000 or more in direct costs for any year must request permission to submit the application at least six weeks before the application receipt date. BRP applicants for projects with direct costs of \$500,000 or more in any year must carry out the following steps:

- 1) At least six weeks before submitting the application (i.e., as you are developing plans for the study), contact a program staff member from an IC which may be appropriate for supporting the project based on its mission to request approval to submit the application. A list of scientific program contacts for participating IC's is available on the Internet at http://www.becon.nih.gov/becon_contacts.htm.
- 2) Obtain agreement from the IC staff member that the IC will accept your application for consideration for award, and,
- 3) Identify the staff member and IC who agreed to accept assignment of the application in the cover letter that transmits the application.

This policy applies to all investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended or revised version of these grant application types. Additional information on this policy is available in the NIH Guide for Grants and Contracts, October 19, 2001, at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>.

All applications that list direct costs of \$500,000 or more per year must also have a data sharing plan.

LETTER OF INTENT: Prospective applicants are asked to submit a letter of intent that includes the following information:

- o Number and title of this PA
- o Descriptive title of the proposed research
- o Name, address, telephone number, and e-mail address of the Principal Investigator
- o List of participating institutions and key personnel

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload, plan the review, and evaluate programmatic impacts of the proposals.

The letter of intent is to be sent by the date listed at the beginning of this document. The letter of intent should be sent to:

Dr. Richard E. Swaja
National Institute of Biomedical Imaging and Bioengineering
6707 Democracy Boulevard, Suite 200
Bethesda, MD 20892-5469
Telephone: (301) 451-4779
FAX: (301) 480-4973
Email: swajar@nibib.nih.gov

BRP ORGANIZATIONAL STRUCTURE, LEADERSHIP, AND MANAGEMENT:

An organizational structure that clearly defines the partnership and relationships among the various components must be developed and described in the application. The BRP size, structure, and mode of operation should match the needs and scope of the proposed research. NIH policy requires that a single PI be designated on the face page of all applications. While this individual is responsible for the scientific and technical aspects, as well as the proper conduct of the project, the structure of the BRP may involve more than one individual in developing the application and in making decisions concerning planning, management, staffing, and resource allocation. In recognition of the essential intellectual and/or technical contributions of the lead scientists responsible for developing and implementing the goals of the proposal, the BRP organizational structure must include a “Leadership Statement” that specifies the roles of the individuals that provide major intellectual and/or technical contributions. The PI has the responsibility and authority to use BRP funds in the most productive way to achieve the goals defined at the time of the award. To accomplish these tasks, the PI in collaboration with other individuals identified in the “Leadership Statement” can adjust funding among BRP participants to support new partners or to reduce support to existing partners as needed. The BRP should establish a Scientific Steering Group that consists of representatives from each of the partnering organizations and meets regularly to discuss project status, problems, and directions. Those individuals identified in the “Leadership Statement”, who together would have the intellectual and leadership responsibilities normally attributed to the PI, would likely be members of the Scientific Steering Group.

BRP PI MEETING: BRP PIs will meet annually in Bethesda, Maryland, to share results, to ensure that the NIH has a coherent view of the advances in these fields, and to have an opportunity for collective problem solving among the PIs. The cost of participating in this annual meeting should be included in the BRP budget.

WHERE TO SEND INQUIRIES

We encourage inquiries concerning this PA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues.

Inquiries or contacts concerning institute-specific scientific, grants management, or financial issues should be directed to the NIH BECON scientific or financial contacts listed at the following Web site: http://www.becon.nih.gov/becon_contacts.htm. The scientific contacts can also be used to obtain permission to submit applications that request \$500,000 or more of direct costs in any year and to discuss specific research focus areas of interest to individual ICs.

Inquiries regarding general BRP programmatic issues should be directed to:

Dr. Richard E. Swaja
National Institute of Biomedical Imaging and Bioengineering/NIH/DHHS
6707 Democracy Boulevard, Suite 200
Bethesda, MD 20892-5469
TEL: 301-451-4779
FAX: 301-480-4973
E-mail: swajar@nibib.nih.gov

Inquiries concerning peer review issues should be directed to:

Dr. Eileen Bradley
Center for Scientific Review/NIH/DHHS
6701 Rockledge Drive
Bethesda, MD 20892
TEL: 301-435-1179
FAX: 301-480-2241
E-mail: bradleye@csr.nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). Applications must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dunandbradstreet.com/>. The DUNS number should be entered on line 11 of the face page of the PHS 398 form. The PHS 398 is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

APPLICATION PREPARATION INSTRUCTIONS: Follow the PHS 398 instructions for "Preparing Your Application" with the following modifications and additions:

The title and number of this program announcement must be typed on line 2 of the face page of the application form, and the YES box must be marked.

1. Page limitations for both new and competing continuation BRP applications have been increased to a maximum of 40 pages from the usual 25-page limit for sections A-D of the "Research Plan". This 40-page limit is an absolute maximum. Applicants are encouraged to be concise and use fewer pages.

2. Description page - In addition to the information requested on Form Page 2, identify in the Description the name(s) of the institution(s) leading the BRP and other participating institutions. The Description should clearly indicate the area(s) of bioengineering research that will be the focus of the BRP, the planned multi-disciplinary approach, and the specific objective of the project.

To provide recognition of the essential contributions of partners who provide significant intellectual leadership to the BRP project, applicants are strongly encouraged to include information about Lead Investigators in the abstract, which is a publicly accessible document. Lead Investigators are those who provide essential scientific, engineering, technical, and visionary leadership to the effort. In the past, applications might have listed such individuals as Key Personnel. Include in the abstract the following information about each Lead Investigator: name, institution if different from the applicant organization, and one sentence about the leadership role. The description of the roles of Lead Investigators should be provided in greater detail in the narrative for personnel in the budget section.

The Lead Investigators will usually include the Principal Investigator and a subset of the Key Personnel. The following information is provided to clarify the roles of the various individuals who are to be named on this page. NIH grants policy requires that each application designate a single Principal Investigator (PI) who (1) is responsible for the overall scientific and technical direction of the effort and (2) serves as the contact person with whom NIH staff will interact. Lead Investigators provide essential scientific, engineering, technical, and visionary leadership to the effort. Key Personnel are those individuals who contribute in a substantive way to the scientific or engineering development or execution of the project.

3. An organization chart (OC) that clearly defines the partnership and relationships among its various components must be included with the application. A program plan (PP) should accompany the OC and list major tasks with a timeline of quantitative milestones for the entire project period. The structure and function of the Scientific Steering Group should be described in this section. The OC and PP must not exceed one page each. This information should be included in the Research, Design, and Methods section of the application.

4. BRP Budget Items - A separate budget for each partner at a subcontract/consortium institution, and when appropriate for clarity, for each partner within the grantee institution must be included. Include a summary budget for all BRP participants with partners at non-grantee institutions shown as consortium arrangements. It is understood that this is an initial budget, and that the PI has the responsibility to reallocate funds during the project to accomplish the BRP goals.

The NIH ICs will not provide annual support in excess of \$2 million total cost for any year for new applications. Direct cost inflationary increases following the first year may be included, but the maximum total cost request level of \$2 million per year must be observed.

The PI is expected to devote a minimum of 25% effort to the BRP. The percent effort requested for all personnel should be limited to time devoted specifically to BRP activities and not to other research projects. Information documenting the level of effort on BRP activities should be included in the application. The need for all requested personnel costs should be thoroughly justified.

There will be an annual BRP PI meeting at a date and location to be determined by NIH staff. Applicants should include travel funds specifically for these meetings in the BRP budget request.

Applicants may request and justify additional travel funds. Travel funds could be used to promote collaboration among BRP partners at different institutions or at a distant site, for travel of external advisors to the BRP site, and/or for BRP partners to attend scientific meetings essential to the progress of the project and for which other funds are not available.

Other expenses can be requested including costs necessary for the central administration and fiscal management of the BRP including relevant and reasonable costs for reprints, graphics, and publications. Administrative support (a secretary or an administrative assistant) may be requested only for matters directly pertaining to the BRP.

With regard to projected funding by source, some BRP applicants may anticipate or receive commitments for significant funding from sources other than the NIH; e.g., from a collaborating company. In this case, applications should describe the source, annual amount, and use of the other funding.

5. Resources - The application should describe the equipment and facilities available for the proposed BRP.

If the BRP entails an institutional commitment of resources across boundaries in the institution or anticipates the provision of institutional resources, letters from appropriate senior-level individuals describing their agreements to support those commitments must be included.

Where appropriate, describe the shared facilities to be established including specific major research instruments and plans for the development of instruments. Describe plans for maintaining and operating the facilities including staffing, provisions for user fees, and plans for ensuring access to outside users. Distinguish between existing facilities and those still to be developed.

6. Research Plan

A. Specific Aims – A BRP may propose design-directed, developmental, discovery-driven, or hypothesis-driven research. Thus, the application should state the hypotheses, designs, problems, and/or needs that will drive the proposed research. Describe the specific aims in the appropriate area of bioengineering research and the milestones for the project period. Describe the expected applications of the bioengineering research that will improve human health. One page is recommended.

B. Background and Significance - Briefly describe the area of bioengineering research that is the focus of the BRP. Critically evaluate existing knowledge and approaches that have been or are being applied in the area and specifically describe how the proposed BRP approach will advance the field. State concisely the importance and health relevance of the research proposed to achieve the Specific Aims.

C. Preliminary Studies and Rationale - Preliminary studies that support the proposed research should be described in the application.

D. Research Design and Methods - A BRP should focus on a systems approach for bioengineering research aimed at a significant advance in biology or medicine. The research plan should be sufficiently long term (five to ten years) and comprehensive to justify organizing a BRP and adaptable enough to permit change as the research proceeds. The integrative systems approach and its appropriateness for the proposed project should be described including plans for collecting, analyzing, and interpreting data. A timetable of events including quantitative milestones or other evaluative criteria should be included. The contributions of each partner and how these will be integrated and organized to accomplish the specific aims of the project should be described. Potential technical challenges and possible alternative approaches to achieve the aims of the project should be discussed. Plans for enhancing the abilities and opportunities for investigators and trainees to work across disciplinary boundaries should also be included. If the proposed BRP research is closely related to ongoing research, explain how the research activities of the BRP will complement but not overlap the existing research.

7. Applications should include a plan for making available to the research community any technologies developed or enhanced by work conducted as part of the program announcement. The plan should include ordering of authors and provision for publication/recognition of the contributions of each essential co-author. This plan should be described in the Research Design and Methods section of the application. Investigators using PHS funds are required to make unique research resources readily available for research purposes to qualified individuals within the scientific community when the results have been published. The intent of this policy is not to discourage, impede, or prohibit the organization that develops the unique research resources or intellectual property from commercializing the products. It is strongly encouraged that technology transfer officials from each participating organization be members of the BRP or the Scientific Steering Group.

APPLICATION RECEIPT DATES: New and competing renewal applications submitted in response to this program announcement will be accepted on January 21, 2004; August 20, 2004; January 20, 2005; August 19, 2005; January 20, 2006; and August 22, 2006. These are the dates that applications must be received at the NIH.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the checklist, and five signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health/DHHS
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

APPLICATION PROCESSING: Applications must be received on or before the receipt dates described as listed on the first page of this announcement. The CSR will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an unfunded version of an application already reviewed, but such application must include an Introduction addressing the previous critique.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within 8 weeks.

PEER REVIEW PROCESS

Applications submitted for this PA will be assigned on the basis of established PHS referral guidelines. Appropriate scientific review groups convened in accordance with the standard NIH peer review procedures (<http://www.csr.nih.gov/refrev.htm>) will evaluate applications for scientific and technical merit.

As part of the initial merit review, all applications will:

- o Possibly undergo a selection process in which only those applications deemed to have the highest scientific merit will be discussed and assigned a priority score
- o Receive a written critique
- o Receive a second level review by the appropriate national advisory council or board

REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of your application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals:

- o Significance
- o Approach
- o Innovation
- o Investigator
- o Environment

The score should reflect the overall impact that the BRP award could have on the selected area of bioengineering research based on consideration of the five criteria given below. The emphasis on each criterion can vary from one application to another depending on the nature of the application and its relative strengths. An application need not be strong in all categories to be judged likely to have major technical or scientific impact and thus deserve a high priority score. For example, an investigative partnership may propose to perform important work that by its nature is not innovative but is essential to advance a field.

A BRP may propose design-directed, developmental, discovery-driven, or hypothesis-driven research at universities, national laboratories, medical schools, large or small businesses, or other public and private entities.

The review criteria include:

1. Significance. If the specific aims of the BRP are achieved, will they provide significant advances in the selected area of bioengineering research? Is the research likely to have a significant impact on other areas of research? Will the technological advances have a significant impact on human health?

2. Approach. Are the BRP engineering, scientific, and clinical approaches and methods adequately developed, well-integrated, and appropriate to the aims of the project? Does the application address potential problem areas and consider alternative strategies? Is a timetable with adequate research milestones proposed? Are appropriate specifications and evaluation procedures provided for assessing technological progress? Is the plan for sharing or disseminating technologies developed or enhanced under this program announcement adequate? Is the plan for technology transfer involving each partnering organization adequate? Does the application describe arrangements that facilitate the fruitful participation of a partner at a distant site? If partnership with industry or small business is included, does this positively affect the research goals and technology dissemination?

3. Innovation. Does the BRP propose new approaches, explore new research

paradigms, or represent new concepts that combine engineering, physical, and clinical sciences? Will the proposed approaches or concepts solve current scientific or technical problems in novel ways?

4. Investigators. Is the PI capable of coordinating and managing the proposed BRP? Are the investigators (partners) appropriately trained in their disciplines and capable of conducting and contributing to the management of the proposed interdisciplinary work?

5. Environment. Does the scientific and technological environment in which the work will be done contribute to the probability of success? Does the proposed research take advantage of unique features of the scientific environment or employ useful collaborative arrangements within the partnership? Is there evidence of institutional support? Does the partnership create potential opportunities to foster trans-disciplinary communication and training across traditional scientific and technical boundaries?

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, your application will also be reviewed with respect to the following:

PARTNERSHIP AND LEADERSHIP: Is the proposed partnership adequate for the research? Is there evidence that the partnership will be effectively managed by the PI or project manager? Is the partnership strategy well planned and documented? Is there evidence that the partners from academia or industry can work together effectively, have an impact on achieving the research goals, and disseminate the developed technology?

PROTECTIONS: The adequacy of the proposed protection for humans, animals, or the environment, to the extent they may be adversely affected by the project proposed in the application.

INCLUSION: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria included in the section on Federal Citations, below)

Sharing Research Data

Applicants requesting more than \$500,000 in direct costs in any year of the proposed research are expected to include a data sharing plan in their application. The reasonableness of the data sharing plan or the rationale for not sharing research data will be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or priority score.

TECHNOLOGY TRANSFER: The adequacy of the proposed plan to integrate technology transfer from the partnering organizations.

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

AWARD CRITERIA

Applications submitted in response to a PA will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

- o Scientific merit of the proposed project as determined by peer review
- o Availability of funds
- o Relevance to program priorities

REQUIRED FEDERAL CITATIONS

HUMAN SUBJECTS PROTECTION: Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>

DATA AND SAFETY MONITORING PLAN: Data and safety monitoring is required for all types of clinical trials, including physiologic, toxicity, and dose-finding studies (phase I); efficacy studies (phase II), efficacy, effectiveness and comparative trials (phase III). The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risk to the participants. (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

SHARING RESEARCH DATA: Starting with the October 1, 2003 receipt date, investigators submitting an NIH application seeking more than \$500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible. http://grants.nih.gov/grants/policy/data_sharing . Investigators should seek guidance from their institutions, on issues related to institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data-sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and

Contracts on October 9, 2001

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>);

a complete copy of the updated Guidelines are available at

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS: The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at

<http://grants.nih.gov/grants/funding/children/children.htm>.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at <http://stemcells.nih.gov/index.asp> and at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see <http://escr.nih.gov>).

It is the responsibility of the applicant to provide, in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.healthypeople.gov/>.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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